



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS AND INTERFERENCES

In re Patent Application of

Debyser et al

Atty. Ref.: 550-392

Serial No. 09/403,625

Group: 1652

Filed: February 7, 2000

Examiner: Fronda

For: INHIBITORS OF CELLULOLYTIC, XYLANOLYTIC AND BETA-GLUCANOLYTIC
ENZYMES

* * * * *

June 7, 2006

Mail Stop Appeal Brief - Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

REPLY BRIEF

The Appellant submits the present Reply Brief, pursuant to 37 CFR § 41.41, in response to the Examiner's Answer dated April 7, 2006.

An Oral Hearing was requested August 29, 2005. The requisite Oral Hearing Request fee was paid August 29, 2005. Nothing further is believed to be required. A separate paper again requesting an Oral Hearing however is provided herewith.

The substance of the Appeal Brief filed April 8, 2005 is incorporated herein by reference. The following further comments are made in response to issues and/or conclusions presented in the Examiner's Answer of April 7, 2006 (hereinafter the Examiner's Answer), as clarification of the record and/or for the convenience of the Board.

(1) The Examiner's reliance on MPEP § 2163

On pages 6 and 9 of the Examiner's Answer, the Examiner reference to

"MPEP 2163, section II. METHODOLOGY FOR DETERMINING ADEQUACY OF WRITTEN DESCRIPTION. Of particular relevance to appealed claims 48-50 and 52-56 is part (3)(C)(i) For Each Claim Drawn to a Single Embodiment of Species (C)(2) which is reproduced below:"

The applicants note that Federal Circuit and Patent Office Board decisions, rather than the MPEP Examination Guidelines, are controlling.

Moreover, the passage of the MPEP reproduced by the Examiner in the Examiner's Answer is believed to be from MPEP § 2163(II.)(A.)(3.)(a)(i)(C)(2) (Rev. 3, August 2005). The undersigned was unable to locate a §2163(II)(3)(C)(i) or §2163(C)(2) of the MPEP.

Further, MPEP § 2163(II.)(A.)(3.)(a) appears to provide Examination Guidelines for "Original claims". The pending claims are believed to be "New Claims", for which Examination Guidelines are believed to be provided by MPEP § 2163(II.)(A.)(3.)(b) ("New Claims, Amended Claims, or Claims Asserting Entitlement to the Benefit of an Earlier Priority Date or Filing Date under 35 U.S.C. 119, 120, or 365(c)").

Finally, the Examiner's repeated reference to claims 48-50 and 52-56 as claims drawn to a "genus" of any xylanase inhibitors (see page 7, line 1 of the non-quoted text, of the Examiner's Answer) is curious within the context of the Examiner's reliance on the Examination Guidelines in MPEP § 2163(II.)(A.)(3.)(a)(i), which relates to guidelines "For Each Claim Drawn to a Single embodiment or Species". MPEP §

2163(II.)(A.)(3.)(a)(ii) appears to provide guidelines for examination of "For each claim drawn to a genus."

Substantively, the passage of MPEP § 2163(II.)(A.)(3.)(a)(i) (Rev. 3, August 2005) which follows the passage cited by the Examiner in the Examiner's Answer provides as follows:

Whether the specification shows that applicant was in possession of the claimed invention is not a single, simple determination, but rather is a factual determination reached by considering a number of factors. Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

The above-quoted passage is similar in substance to the passage quoted in the Appeal Brief on pages 23-25.

The passage emphasized by the Examiner spanning pages 6-7 of the Examiner's Answer (i.e., "In contrast, without such a correlation [between structure and function], the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In this latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement.") is believed to be contrary to the courts prohibition against *per se* rules. See *Falko-Gunter Falkner v. Inglis*. Fed Cir., No. 05-1324, 5/26/06

at page 14 and Capon v. Eshhar. Fed. Cir., No. 03-1480, -1481, 8/12/05, p. 20.

Moreover, the quoted passage of the MPEP is understood to relate to a determination of written description support where only a function and partial structure are provided. The presently claimed invention however is defined in the specification and claims by a number of identifying characteristics that distinguish the claimed invention from other materials and would lead one of ordinary skill in the art to the conclusion that the appellants were in possession of the claimed invention.

The Patent Office allowance of claims to a protein defined by a combination of function and partial N-terminal sequence in Interference No. 103,625, and the involved U.S. Patent No. 5,344,915, is consistent with the appellants reliance on and interpretation of the previously quoted case law. See, LeMaire v. Wallach, USPTO BPAI, Interference No. 103,625, Paper No. 105, Heard: February 2, 2000, available at <http://des.uspto.gov/Foia/BPAIReadingRoom.jsp>.

(2) The unsupported assertions of the Examiner should be given no weight

The Examiner's provides the following unsupported assertion on pages 7-8 and 12 of the Examiner's Answer:

"The scope the genus [sic] includes many proteins or glycoproteins with widely differing structure, chemical, biological, and physical characteristics. Furthermore, the genus is highly variable because a significant number of structural differences between genus members exist....

The scope of the genus includes many proteins or glycoproteins with widely differing structural, chemical,

biological, and physical characteristics with no limitations on the composition of their amino acid sequences. Furthermore, the genus is highly variable because a significant number of structural differences between genus members exists.”

The Examiner has not provided any evidence to support the above-quoted characterizations of the claimed products. The unsupported assertions of the Examiner should be given no weight.

(3) The Examiner’s restatement of the written description requirement is not supported by the law, rules or MPEP.

Specifically, the Examiner asserts the following:

“To fully describe this claimed genus the specification must fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus.” See, the paragraph spanning pages 12-13 of the Examiner’s Answer.

The law does not require one to visualize or recognize or predict the structure of other species of a claimed genus, but rather the law requires that the claimed invention be adequately described so as allow one of ordinary skill in the art to visualize or recognize the identity of members of the genus. For some biomolecules, examples of identifying characteristics include a sequence, structure, binding affinity, binding specificity, molecular weight, and length. Although structural formulas provide a convenient method of demonstrating possession of specific molecules, other identifying characteristics or combinations of characteristics may demonstrate the requisite possession. For example, unique cleavage by particular enzymes, isoelectric points of

fragments, detailed restriction enzyme maps, a comparison of enzymatic activities, or antibody cross-reactivity may be sufficient to show possession of the claimed invention to one of skill in the art. See *Lockwood*, 41 USPQ2d at 1966, as quoted on page 24 of the Appeal Brief.

The Examiner's assertion that the application must describe a species sufficient to allow prediction of the structure of other species of a claimed genus is an incorrect and unsupported characterization of the law.

Conclusion

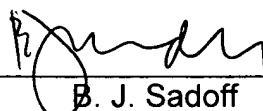
For the reasons provided in the entire record, including the appellants' Appeal Brief filed April 8, 2005, reversal of the 35 U.S.C. § 112, first paragraph "written description", rejection of claims 48-50, 52-56 and 65-68 is requested.

The application is submitted to be in condition for allowance and Reversal of the Final Rejection is requested.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____



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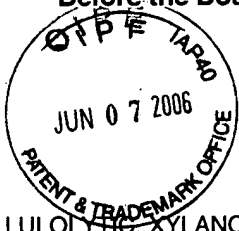
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Handwritten initials: HF ZW

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☐ **Correspondence Address Indication Form Attached.**

☐ **NOTICE OF APPEAL**

Applicant hereby **appeals** to the Board of Patent Appeals and Interferences
from the last decision of the Examiner twice/finally rejecting
applicant's claim(s).

\$500.00 (1401)/\$250.00 (2401) \$

☐ An appeal **BRIEF** is attached in the pending appeal of the
above-identified application

\$500.00 (1402)/\$250.00 (2402) \$

☐ Credit for fees paid in prior appeal without decision on merits

-\$ ()

☒ A reply brief is attached.

(no fee)

☐ Petition is hereby made to extend the current due date so as to cover the filing date of this
paper and attachment(s)

One Month Extension \$120.00 (1251)/\$60.00 (2251)

Two Month Extensions \$450.00 (1252)/\$225.00 (2252)

Three Month Extensions \$1020.00 (1253)/\$510.00 (2253)

Four Month Extensions \$1590.00 (1254)/\$795.00 (2254) \$

☐ "Small entity" statement attached.

Less month extension previously paid on

-\$ ()

TOTAL FEE ENCLOSED \$ 0.00

Any future submission requiring an extension of time is hereby stated to include a petition for such time extension.
The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or
asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this
firm) to our **Account No. 14-1140**. A duplicate copy of this sheet is attached.

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Signature: _____

Handwritten signature of B. J. Sadoff